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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087.	9337

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DARA L DINNER  
SMITHKLINE BEECHAM CORPORATION  
CORPORATE INTELLECTUAL PROPERTY UW2220  
709 SWEDELAND ROAD  
KING OF PRUSSIA, PA 19406-0939

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/600,673

Applicant(s)

DAGGY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. The amendment filed April 11, 2002 (Paper No. 6) is acknowledged. Claims 3, 6-9, 12 and 15-18 have been amended.

Claims 1-18 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Withdrawn:***

3. The rejections of claims 1-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of the amendment.

#### ***Claim Rejections Maintained:***

4. The rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record.

The basis for this rejection is that the disclosure of four species of cellulose derivatives is not adequate to describe the full scope of the cellulose derivatives as recited in claims 1 and 10. Because the scope of the term "derivative" includes fragments, fragments that may be as small as

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one atom of a cellulose molecule, the multitude of structures encompassed by the phrase “cellulose derivative” is large and includes structures of that have little in common structurally. Thus, the disclosure of four species of cellulose derivatives is not representative of the genus of cellulose derivatives encompassed by claims 1 and 10. Thus, the methods of claims 1 and 10 are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Applicant’s arguments have been carefully considered but are unpersuasive. Applicant argues that it is not the number of species in the specification that is important but that a suitably descriptive term is used that enables the skilled artisan to contemplate the proposed breadth of the claimed invention. This argument is not persuasive in this case because the term “cellulose derivative” may be interpreted to include structures that have little in common structurally with the exemplified compounds. Thus, the four species of cellulose derivatives are not representative of the genus of cellulose derivatives encompassed by claims 1 and 10.

5. The rejection of claims 1-3, 5-12 and 14-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the combination of fibers includes the addition of wheat bran to cellulose, does not reasonably provide enablement for methods where the combination of fibers lacks wheat bran is maintained for the reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Applicant's arguments are unpersuasive because the working example in the specification demonstrates that the combination of methylcellulose with wheat bran have a synergistic effect over the administration of either methylcellulose or wheat bran alone. Therefore, the specification fails to provide any evidence or teachings for the treatment of combinations of fibers where the combination lacks wheat bran. Applicant argues that the specification provides teachings for how to make combinations of fibers, including combinations lacking wheat bran, but fails to show specifically where in the specification such support may be found.

Claims 1-3, 5-12 and 14-18 are broadly drawn to methods of administering combinations of fibers to mammals for reducing the incidence of either colon cancer or breast cancer, where the combinations may or may not include wheat bran. The specification provides support for the claimed methods by demonstrating that a combination of methylcellulose and wheat bran fibers have a synergistic effect over the administration of methylcellulose alone or wheat bran alone. The specification fails to provide any support for methods where the combination of fibers would comprise methylcellulose and psyllium, without the addition of wheat bran. Thus, claims 1 and 10, which recite "in combination with an insoluble fiber and/or a soluble fiber", are not supported to the extent that the combination of fibers may be two soluble fibers (methylcellulose and psyllium).

The prior art appears teaches that combinations of soluble and insoluble fibers are synergistic in the reduction of colon cancer risk and breast cancer risk (see Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al. Cancer Letters 75: 53-58, 1993; cited in the IDS). There does not appear to be teachings in the prior art that would support methods for combining two soluble fibers.

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In view of the breadth of the claims, the support provided by the specification and the teachings of the prior art, it appears that undue experimentation would be required to practice the claimed methods to the extent that they read on administering combinations of two soluble fibers without the addition of an insoluble fiber.

6. The rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 102(e) as being anticipated by Annison et al (U.S. Patent 5,840,860; issued 11/24/1998; effective filing date for 102(e) 9/5/1996) is maintained for the reasons of record.

Applicant argues that because Annison teaches a method comprising the administration of short chain fatty acid covalently bonded to cellulose, so that Annison's method results in the delivery of short chain fatty acids to the lower bowel, that Annison's method does not anticipate the claimed inventions because the claimed inventions are drawn to methods comprising administration of non-fermentable cellulose derivatives, where a non-fermentable cellulose derivative is a cellulose derivative that is not fermented to short chain fatty acids. However, the claims do not recite that the methods exclude the delivery of short chain fatty acids to the bowel. Furthermore, as discussed above, because of the broad term "cellulose derivative", Annison's compound falls within the scope of the compounds used in the claimed methods. Therefore, Annison teaches a method within the scope of the claimed methods.

Annison teaches a method comprising the administration of a short chain fatty acid covalently bonded to a cellulose (reads on a cellulose derivative). Annison teaches that the method may be used for lowering the risk of a colon disorder such as colonic cancer (see claims 24-26, col. 24). Annison also claims that the cellulose may be in the form of methylcellulose of

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hydroxypropylmethylcellulose (see claim 31). Annison teaches that the esterified cellulose may be formulated into a powder or tablet form, teaches ranges of dosages that are within the claimed ranges (see column 8, lines 7-17, lines 37-42; column 23, lines 1-3). Thus, Annison teaches and claims methods that are the same as that claimed.

7. The rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 102(b) as being anticipated by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995) is maintained for the reasons of record.

Applicant appears to be arguing that Folino fails to demonstrate that non-fermentable water soluble cellulose fibers are more efficacious than other dietary fibers, and therefore, Folino fails to teach the claimed methods. However, Folino teaches a method comprising the same steps as those of the claimed methods. Therefore, Folino anticipates the claimed methods.

Folino teaches a method of administering methylcellulose to rats (see page 1522, 1<sup>st</sup> column, and Table I, page 1523). Folino teaches that the methylcellulose accounted for 1 gm of the total fiber (see Table 1). The methylcellulose appears to be administered in the form of a suspension (see notes of Table 1). Thus, Folino teaches a method that is the same as that claimed.

8. The rejection of claims 10, 11, 14, 15, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over either Annison et al (supra) or Folino et al (supra) in view of Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) is maintained for the reasons of record.

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Applicant's arguments are unpersuasive for the reasons stated above with respect to the teachings of either Annison or Folino. The teachings of Cohen are relied upon to demonstrate that it is known in the art that breast cancer, in addition to colorectal cancers, are treatable by the administration of dietary fibers.

9. The rejection of claims 1, 4, 10 and 13 under 35 U.S.C. 103(a) as being unpatentable over Annison et al (supra) or Folino et al (supra) in view of either Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al., Cancer Letters, 75: 53-58, 1993; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments are unpersuasive for the reasons stated above with respect to the teachings of either Annison or Folino. The teachings of Cohen or Alabaster are relied upon to demonstrate that it is known in the art to combine soluble and insoluble fibers, and that such combinations have a synergistic effect in colon or breast cancer risk reduction.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period



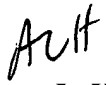
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

  
Anne L. Holleran  
Patent Examiner  
June 30, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600